



NATIONAL CENTER FOR COMPLEMENTARY
AND ALTERNATIVE MEDICINE

National Center for Complementary and Alternative Medicine

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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INTRODUCTION

Our Mission

The mission of NCCAM is to define, through rigorous scientific investigation, the usefulness and safety of complementary and alternative medicine interventions and their roles in improving health and health care.

Our Vision

Scientific evidence informs decisionmaking by the public, by health care professionals, and by health policymakers regarding use and integration of complementary and alternative medicine.

The National Center for Complementary and Alternative Medicine (NCCAM) is the Federal Government's lead agency for research on complementary and alternative medicine (CAM). There are many definitions of CAM, none of them perfect. NCCAM defines it simply as a group of diverse medical and health care systems, practices, and products that are not generally considered to be part of conventional medicine. Clearly the boundaries between CAM and conventional medicine (also called Western or allopathic medicine) are not absolute. For example, interventions such as hospice care or relaxation and breathing techniques in childbirth that were once considered unconventional are now widely accepted, and CAM interventions are often incorporated into integrative medicine practices. In addition, data from national surveys suggest that CAM is most often used by the general public as complementary or adjunctive to conventional medical care.

Since its creation as an independent Center at the National Institutes of Health (NIH) in 1998, NCCAM has twice developed strategic plans to help guide the implementation of its legislative mandate. Building on 10 years of scientific progress, a robust research enterprise, and strong collaborations across the NIH, NCCAM is now shaping its future through this third comprehensive strategic plan, developed with thoughtful input from its diverse stakeholder community.

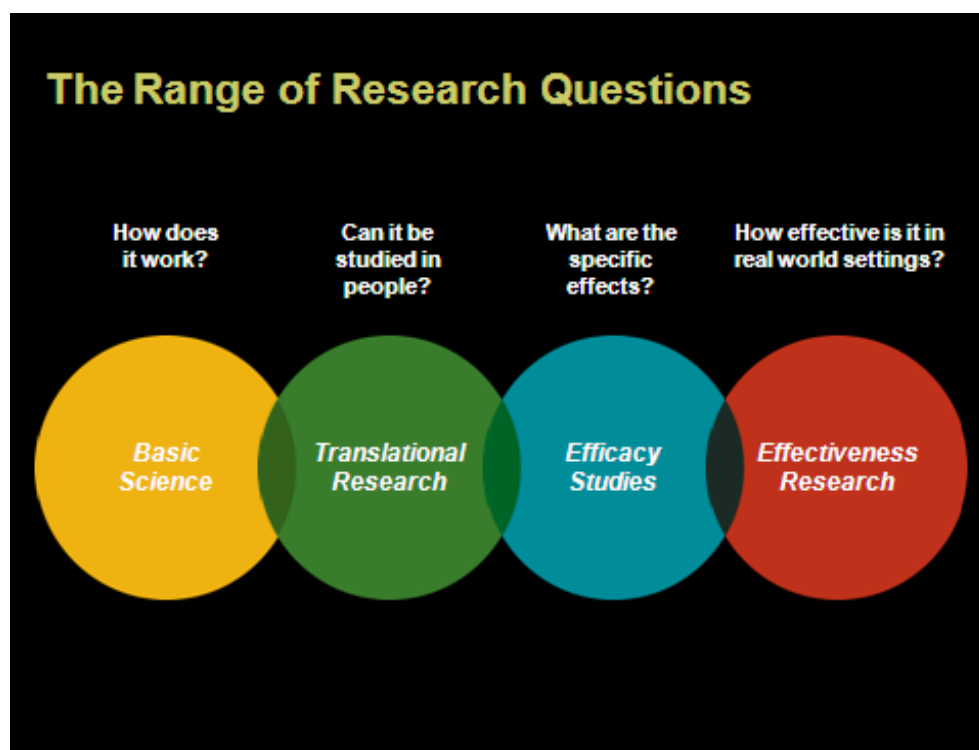
Over a year-long planning process, NCCAM carefully assessed how recent developments in science, medicine, and health care have affected the Center's strategic approaches in this broad and diverse arena of health care and health promotion interventions. This assessment has led to four important conclusions.

First, there is a compelling need for greater focus in setting research priorities. This conclusion stems from (1) the insight gained over the past 10 years into specific areas of promise in addressing important public health needs and (2) from the recognition that finite resources are available to pursue those opportunities that have the greatest potential for adding significant value to the public health.

Second, one of those areas of promise and need is in treating chronic pain. National survey data show that the vast majority of Americans' use of CAM to treat specific health problems is aimed at ameliorating symptoms, particularly chronic pain. Furthermore,

emerging data from the past 10 years point toward specific scientific opportunities for research with the potential to contribute to better approaches for care and treatment of chronic pain in addition to those currently available and employed in conventional medicine.

Third, it has become clear that CAM modalities—whether pharmacological or mind/body and manual/manipulative—can and must be studied across the continuum of basic, translational, efficacy, and effectiveness research.



This means a continued emphasis on research to understand biological effects and mechanisms is needed to design definitive clinical intervention studies and to better inform the scientific evidence base. It also means strengthening “real-world” effectiveness research approaches that draw—and capitalize—on the reality that many CAM interventions are in very widespread public use, and some have been for centuries.

Finally, the strategic planning process forged a realization that although half of CAM use by Americans is aimed at improving general health, most CAM research to date has focused on the application of CAM practices to the treatment of various diseases and conditions. Greater emphasis on measures to promote and improve health and well-being (as contrasted to treatment or prevention of disease) are desired by and important to everyone and are a prime focus of current efforts to improve health care in America. While there are significant scientific and logistical challenges in pursuing a health-promotion research agenda, there are compelling opportunities to explore the potential role of many CAM practices and interventions.

Goals of the Strategic Plan

This strategic plan describes NCCAM's plans to further develop its efforts in the important goals of identifying CAM interventions to improve symptom management, to promote greater well-being, and to sustain a healthier lifestyle. In consideration of the larger challenges and opportunities, this third strategic plan offers three overarching goals for the next 5 years and beyond.

GOAL 1: Advance the science and practice of symptom management.

CAM approaches are most often used to manage pain and other symptoms of underlying diseases and conditions, including chronic back pain, arthritis, anxiety, and insomnia, usually in conjunction with conventional medical strategies. There is growing evidence that some modalities are helpful—for example, massage, chiropractic manipulation, and acupuncture for chronic back pain, or acupuncture for chemotherapy-induced nausea—and that they engage innate biological processes involved in pain and emotion. Research to understand more clearly whether and how such interventions add value to existing approaches and to identify the biological mechanisms by which they exert beneficial effects will advance the science and practice of symptom management.

GOAL 2: Develop effective, practical, personalized strategies for promoting health and well being.

It is widely accepted and generally well established that sustaining behaviors such as healthy eating and regular physical exercise and changing unhealthy behaviors (e.g., smoking cessation) promote health. There is newly emerging evidence that Americans' CAM use is associated with a greater degree of health-seeking behavior. There are also claims and preliminary evidence of success by CAM and integrative medicine practitioners in motivating people to adopt and sustain health-seeking behavior. Examples include use of meditative and other mind/body approaches, physical activities like yoga, and approaches to healthy eating that may be grounded in traditional medical systems or incorporate a healthy food philosophy. While causal relationships have not been established, such data and claims deserve investigation, particularly given the formidable public health challenges in motivating change in health-related behaviors. For example, research is needed to explore, clarify, and examine the hypothesis that certain CAM approaches or practices can, in fact, be useful in encouraging better self-care, an improved personal sense of well-being, and a greater commitment to a healthy lifestyle.

GOAL 3: Enable better evidence-based decisionmaking regarding CAM use and its integration into health care and health promotion.

The need—by both consumers and health care providers—for reliable, objective, evidence-based information regarding CAM remains compelling. Addressing that need remains central to NCCAM's success in fulfilling its legislative mandate. Importantly, during the past several years, there is evidence that CAM research findings have influenced CAM use and practice. NCCAM not only will continue to support the best and most promising CAM

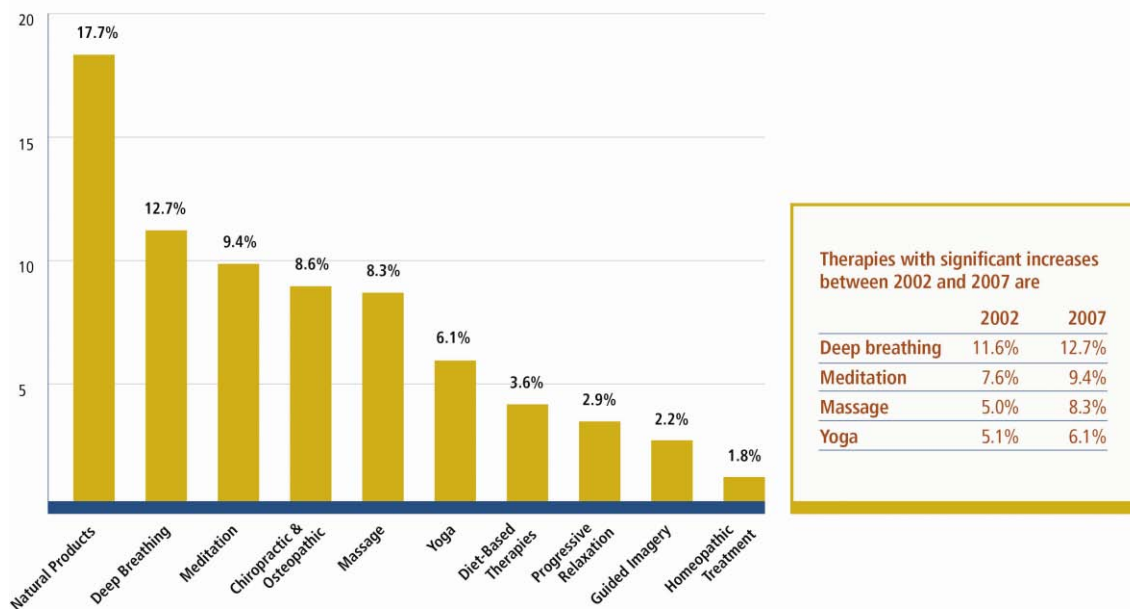
research, but also will continue to provide world-class evidence-based information on the CAM practices used by millions of Americans.

NCCAM enters its second decade at a time of both exciting scientific opportunity and heightened potential for making valuable contributions to health care practice and health promotion. Given the reality of finite resources available to address these opportunities and the scientific and operational challenges facing the field, NCCAM and the broader community of CAM researchers must focus their efforts on specific opportunities with the greatest potential to improve public health and well-being and actively seek collaborations with a variety of public and private partners.

Americans' Use of CAM

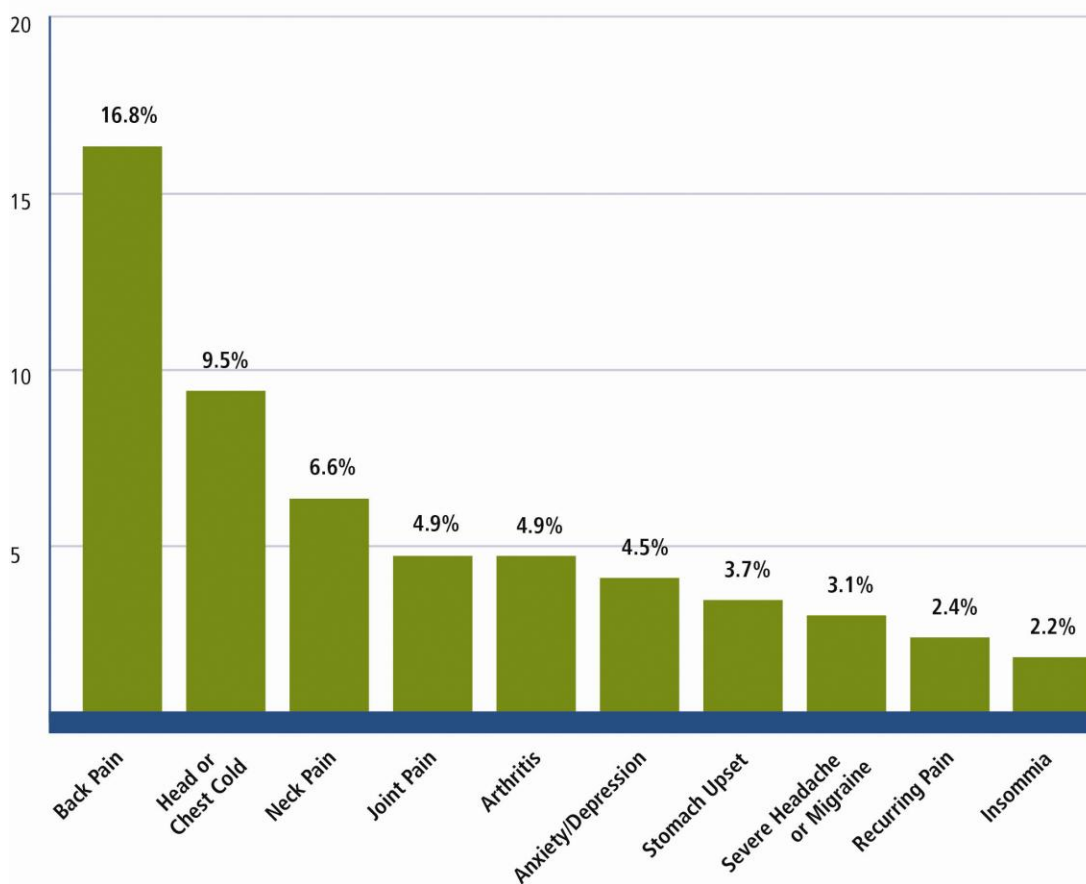
The most current and comprehensive picture of Americans' use of CAM has been developed under NCCAM leadership through the 2002 and 2007 National Health Interview Surveys, conducted by the National Center for Health Statistics at the Centers for Disease Control and Prevention. Across both surveys, CAM use remained generally constant and relatively high, with approximately 38 percent of adults reporting use of some form of CAM. The most commonly used CAM therapies were nonvitamin, nonmineral, natural products (17.17 percent); deep breathing exercises (12.7 percent); meditation (9.4 percent); chiropractic or osteopathic manipulation (8.6 percent); massage (8.3 percent); and yoga (6.1 percent). NHIS data also provided important insights into reasons for CAM use, which fall into two approximately equal categories: (1) treating a variety of health problems—particularly chronic pain and other difficult symptoms and (2) promoting wellness and prevention.

10 Most Common CAM Therapies Among Adults - 2007



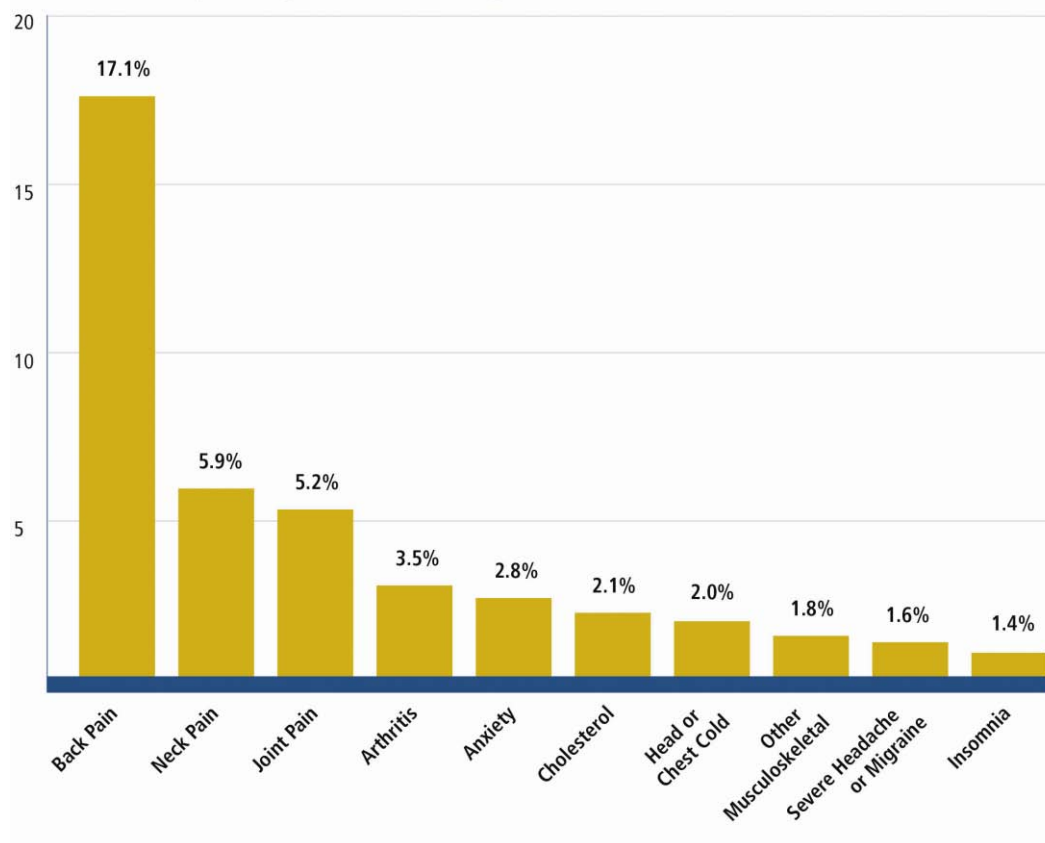
Source: Barnes PM, Bloom B, Nahin R. *CDC National Health Statistics Report #12. Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007*. December 2008.

Diseases/Conditions for Which CAM Is Most Frequently Used Among Adults - 2002



Source: Barnes P, Powell-Griner E, McFann K, Nahin R. *CDC Advance Data Report #343*. Complementary and Alternative Medicine Use Among Adults: United States, 2002. May 2004.

Diseases/Conditions for Which CAM Is Most Frequently Used Among Adults - 2007



Source: Barnes PM, Bloom B, Nahin R. *CDC National Health Statistics Report #12. Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007*. December 2008.

In addition to providing comparison data of CAM use patterns between 2002 and 2007, the 2007 survey also provided extensive data on costs and expenditures. Americans spent \$33.9 billion out-of-pocket for CAM in 2007, accounting for approximately 1.5 percent of total health care expenditures but over 11 percent of total out-of-pocket expenditures on health care. Importantly, about one-third of the total \$33.9 billion was spent on practitioner visits (mostly associated with manipulative and body-based therapies), while nearly two-thirds was spent on a variety of CAM products, classes, and materials not specifically recommended by a health care provider or CAM practitioner (referred to here as “self-care”). A total of 44 percent of all out-of-pocket costs for CAM was spent on the purchase of nonvitamin, nonmineral, natural products.

These patterns of use by the public for a variety of purposes will be central considerations in NCCAM’s strategic planning and research priorities. Moreover, the scope of use and associated costs reinforce the need to ensure the public has access to accurate and timely evidence-based information concerning the safety and efficacy—or lack thereof—of CAM interventions.

Payoffs From Previous NCCAM Investments

Growth of the Evidence Base

Two overarching research priorities of NCCAM's first decade addressed (1) the relative paucity of foundational scientific information on the biological properties, safety, and efficacy of most CAM modalities, and (2) the need for clinical trials testing the efficacy and safety of selected CAM interventions frequently used by the public. The products of this investment include, first and foremost, an emerging evidence base—which has grown substantially in both quality and quantity—regarding efficacy and safety of CAM practices. Basic research and clinical trials, large and small, have yielded results—both “positive” and “negative”—regarding the effects, efficacy, safety, and in some cases, promise regarding CAM. Formal evidence-based analyses and systematic reviews by independent organizations (e.g., the Cochrane Collaboration) point increasingly toward helpful conclusions regarding safety and efficacy or lack thereof of specific CAM products or practices, and these conclusions are influencing practice guidelines of professional medical societies. That the emerging evidence base about CAM is also important to consumers is suggested by evidence that the research has influenced the public's patterns of CAM use. NHIS data and industry sales figures suggest that the results of several large “negative” clinical trials have preceded declines in the frequency of use and sales of selected nonvitamin/nonmineral dietary supplements. In addition, emerging evidence pointing toward the potential value of other supplements has been accompanied by increased public use. Finally, in direct response to the results of NCCAM-funded research, the U.S. Food and Drug Administration has taken actions to address concerns about the safety of several specific CAM products.

Areas of Scientific Promise

Although much attention in both the popular media and scientific community has been given to the “negative” results of several large clinical trials (e.g., Echinacea, glucosamine/chondroitin, and Ginkgo), a large body of intriguing evidence from smaller studies points toward promising opportunities to incorporate CAM interventions into health care and health promotion. In looking forward, it is essential to take stock of the current state of this evidence. Some illustrative examples of these promising leads include insight gained into the following:

- Potential application of specific CAM approaches to comprehensive strategies for management of chronic pain.
- Molecular targets of dietary small molecules (e.g., quercetins, curcumin, and other polyphenols and flavonoids).
- Anti-inflammatory actions of omega-3 fatty acids at clinically relevant concentrations.
- Effects of cranberry juice on bacterial adherence.
- Availability of tools and methods to study the effects of probiotics on the human microbiome.

- Associations between acupuncture or placebo analgesia and known and well-characterized endogenous opioid and other pain-processing pathways.
- Apparent engagement of major pathways of cognition and emotion regulation by meditative practices.
- Importance of the practitioner-patient interaction, context effects, and the placebo response.
- Safety and potential toxicity of widely used herbals and other dietary supplements.

Mapping the Path Forward

To advance the science of CAM toward potential applications that will improve health and well-being, the following guideposts have been identified to keep progress on track.

First, targeted research and development efforts are required in selected instances to ensure progress. A relatively broad, nontargeted, investigator-initiated, research project grant approach was appropriate when NCCAM was a new Center and its overarching goals were to develop foundational evidence and to build multidisciplinary research capacity where little existed. As a result, NCCAM's "unsolicited," investigator-initiated, research project grant stream is increasingly robust. Today, however, this approach cannot solely be relied on to ensure that major gaps in knowledge are filled, or that development of a definitive evidence base regarding specific, important, and promising research leads are pursued with goal-oriented clarity, timeliness, and efficiency.

Second, basic research to increase mechanistic understanding of CAM modalities remains essential. It has become clear that the design of maximally informative clinical research and the interpretation of results from it require a hypothesis grounded in an understanding of biological effects of the intervention. It also requires the concomitant study of the effect of the intervention on biological effects relevant to the hypothesized mechanisms of action. Such information is also an important component of an informative evidence base.

Third, large clinical trials or effectiveness studies require a solid translational research foundation. For example, purely historical information regarding dose, frequency of administration, or even choice of product cannot be relied on as a sufficient basis for a large clinical trial of a dietary supplement. Similarly, research on many mind/body or manipulative practices may require development of treatment algorithms or validation of clinical measures before large-scale trials are initiated.

Fourth, research on the application of CAM modalities to health care and health promotion requires use of effectiveness and other "real-world" research methodologies. Most CAM interventions are readily available to the public and are already incorporated into health care and health practices. This fact points toward the need to employ effectiveness research approaches to answer important questions about the contributions of these modalities to treatment and health promotion. It also points toward

a need for increased collaboration with experts in clinical effectiveness research and in other methodological approaches used to study other procedures or other multi-component interventions (e.g., surgery, psychotherapy, and behavioral change) who confront similar challenges and opportunities.

Fifth, while a vast amount of information about CAM is available to the public, much of it is incomplete, misleading, inaccurate, or based on scientifically unproven claims. In addition, much use of CAM occurs in the absence of health care provider advice. Given this fact and the ready availability and widespread public use of CAM, NCCAM has a special role in providing reliable, objective information based on scientific evidence so that consumers can make informed decisions.

Framework for Priority Setting

Four factors have been identified as being of paramount importance in setting research priorities that are aligned with NCCAM's mission and legislative mandates.

- **Scientific Promise:** Is there a reasonable body of evidence that the proposed research initiative or project has the potential to contribute to (1) available options for treatment of troubling or prevalent health conditions or symptoms, (2) approaches in pursuit of better health and well-being, or (3) currently available research methods or technology?
- **Amenability to Rigorous Scientific Inquiry:** Is the research or development question amenable to rigorous scientific investigation, given available methods, tools, and technologies? Will the project or program develop better and needed research tools and technologies? Are potential approaches feasible and scientifically plausible, and do they lend themselves to rigorous quality control?
- **Potential To Change Health Practices:** Is there reasonable likelihood that the results of the project or program could lead to changes in the health practices of consumers or health care providers or in the decisions of health policymakers?
- **Extent and Nature of Practice and Use:** Does the research address an important public health concern or information need regarding efficacy, safety, or public use? Will the research project or program provide important and needed information about the frequency and nature of CAM use by practitioners or the general public?

This framework is intended to assist NCCAM and its National Advisory Council in articulating the highest priority areas for CAM research and in periodically modifying research priorities as the dynamic field of CAM research continues to evolve.

Strategic Objectives

NHIS data and other studies show that Americans use CAM for a variety of purposes, often with multiple aims. For example, yoga or meditation might be used to help control blood pressure, enhance musculoskeletal flexibility, lessen stress, or achieve a greater sense of well-being. Natural products might be used to treat specific symptoms (e.g., colds or other infections), prevent future illness (e.g., cardiovascular disease), or improve overall health.

To study the effects and effectiveness of CAM modalities in all their diverse and complex environments, NCCAM is organizing its research portfolio around five broad strategic objectives, each of which will serve, to varying degrees, the overarching goals of this plan:

Strategic Objective 1: Advance research on CAM pharmacological interventions.

Strategic Objective 2: Advance research on mind/body and manipulative/manual CAM interventions and practices.

Strategic Objective 3: Increase understanding of “real-world” patterns and outcomes of CAM use and its integration into health care and health promotion.

Strategic Objective 4: Improve the capacity of the field to carry out rigorous research.

Strategic Objective 5: Develop and disseminate objective, evidence-based information on CAM interventions.

STRATEGIC OBJECTIVE 1: ADVANCE RESEARCH ON CAM PHARMACOLOGICAL INTERVENTIONS

Herbal medicines, botanicals, probiotics, and other such orally or topically administered substances (referred to in this plan as CAM natural products (NPs) or CAM pharmacological interventions¹) comprise the most commonly used class of CAM within the United States. They are widely marketed and readily available, often sold as dietary supplements. Although research has explored many of these products, in most instances there is insufficient scientific evidence regarding efficacy or safety to support or refute their use. Nonetheless they are used both for the treatment of health problems or as a means to improve or maintain general health. Herbal medicines and botanicals are also prominent elements of virtually all systems of traditional medicine, and the vast body of documented and verbal history experience with them often is cited as a potential source of leads for further scientific investigation.

Responding to Unmet Needs

In recent years, several issues have emerged that are critical to defining future directions for NCCAM-funded research on CAM pharmacological interventions.

Need for Mechanistic Research and Signatures of Biological Effect

During NCCAM's first decade, a number of large randomized efficacy trials of CAM pharmacological interventions were launched. In most cases, study design was based on a combination of clinical experience and preliminary studies. Generally, however, the studies failed to show hypothesized clinical outcomes. As a result, many questions about key aspects of study design (e.g., choice of product, dose, schedule of administration, outcome measures) have been raised in retrospect, casting uncertainty about the validity of the observed "negative" findings. Thus it has become clear that maximally informative clinical efficacy studies of CAM pharmacological interventions must be based on a scientifically sound hypothesis grounded in basic mechanistic research. In addition, the level of mechanistic insight should be sufficient to allow measurement of signatures of biological effect, biomarkers, or surrogate markers relevant to the hypothesis, in addition to clinical outcome. This approach also will elucidate leads for further research and development.

¹ Terminology: For the purposes of this plan, the labels "CAM pharmacological" and "CAM natural product (NP)" are used interchangeably. The former was chosen because of the central role of the basic, translational, and clinical research tools and methods of the discipline of pharmacology; the latter because many of these interventions have herbal or botanical medicine roots. The term "biologically based" has been abandoned because other CAM modalities have and/or exert biologically based effects.

Need for Both Exploratory Research and Targeted Development

A fully developed research program investigating CAM pharmacological interventions begins with exploratory basic or clinical studies that have potential to yield new, fundamental, mechanistic or physiological insight into the potential value of NP interventions in treating conditions or improving health. This work would include, for example, both the investigation of previously unstudied CAM NPs as well as additional research on previously studied products. It also would allow for serendipitous discoveries about previously unknown biological effects or applications of NPs. The range of products that are appropriate for exploratory research is extensive, and this work is properly supported through investigator-initiated research project grants.

Both the pursuit of promising information derived from basic and exploratory studies and more advanced clinical research require translational research and the development of various translational tools (e.g., key pharmacological studies or the development of sensitive measures of biological activity).

At the far end of the research and development continuum are studies of CAM NPs that warrant targeted and goal-directed development through maximally informative (often large) clinical studies. Given available resources, the expectation is that the number of CAM pharmacological interventions entering large, advanced clinical trials will be small and that these NPs will have been designated high priority by NCCAM because of particularly promising preliminary results in smaller studies or because of a compelling public health need (e.g., safety information).

Historically, NCCAM has supported the vast majority of basic and translational research and development activities relevant to CAM NPs through general solicitations for investigator-initiated research grants. This broad-based approach has yielded a large body of basic mechanistic information and promising leads for future research. Going forward, it has become clear that NCCAM must establish specific priorities and activities—including targeted and directed research and development—in the areas of translational and clinical research to ensure critical gaps in the development of selected specific interventions are addressed and an evidence base is developed.

Need for Continued Attention to Product Integrity and Safety

Historically, NCCAM has placed an emphasis on the quality and integrity of CAM NPs being studied in NCCAM-supported research. During its first decade, NCCAM led NIH in establishing rigorous standards and policies regarding the integrity of products used in both mechanistic and clinical research. The overarching goal of these efforts has been to provide the investigator, NCCAM, and the research community with the requisite level of confidence that the research will yield both definitive and reproducible results. Modifications of NCCAM's Product Integrity Policy have recently been published (<http://nccam.nih.gov/research/policies/naturalproduct.htm>). These more clearly link the level of informational detail required for a natural product to be used in clinical studies.

Nonetheless, there remain major unaddressed needs for improved methodology for characterizing and analyzing CAM NPs.

Furthermore, it remains true that there is limited information about the safety profile of most CAM NPs, including data about inherent toxicity or interactions with drugs or other NPs. Claims that these products have fewer side effects or are “safer” than conventional pharmaceutical alternatives are generally unproven and sometimes erroneous, as well-documented by recent reports of adverse herb-drug or herb-herb interactions, product contamination, or product adulteration.

Strategies for Addressing Scientific Challenges

The primary scientific challenge in studying CAM pharmacological interventions is bringing the available and emerging tools, technologies, and approaches of the pharmacological sciences to bear on the study of chemically and biologically complex interventions and approaches. For example, many of the components in botanical products are complex molecules with low bioavailability (the quantity or fraction of the ingested dose that is actually absorbed). Some of these molecules are metabolized by gut microflora, digestive enzymes, or other biological processes, generating compounds that may be more or less readily absorbed or bioactive. Little is known, however, about their possible bioactivity or the organisms or processes that produce them.

Increasingly, however, researchers are taking advantage of the unprecedented scientific opportunities now available to better understand the biological effects of these products, to more effectively study their potential to contribute to health and well-being, and perhaps to identify promising leads for new therapies. Application of state-of-the-art technologies and systems biology approaches, such as those applied to high-throughput screening and to studies of epigenomics and the microbiome, are particularly promising.

Strategy 1.1: Harness state-of-the-art “omics” and other high-throughput technologies and systems biology approaches of the pharmacological sciences in the study of CAM pharmacological interventions to:

- **Identify biological effects.**
- **Define mechanisms of action.**
- **Elucidate relationships with host biology.**
- **Build a solid biological foundation for translational research needed to carry out clinical studies.**

These tools and technologies also offer promise for sorting out the complexities and validity of theoretical but largely unsubstantiated multi-component (e.g., additive, synergistic, or complementary) mechanisms that are at the core of many herbal traditions, which often combine dietary and supplemental pharmacological approaches. For example, greater clarity about the activity of individual components should facilitate study of possible synergistic effects. In addition, better tools are needed to qualitatively, quantitatively, and

comprehensively capture the chemical diversity of complex (e.g., plant) NPs. For example, most of the techniques for the standardization and characterization of plants focus on the analysis of a limited number of abundant or easily detected and measured “marker” compounds, which may or may not be relevant to the plant’s ultimate biological or clinical effects.

Strategy 1.2: Support translational research to build a solid biological foundation for research on CAM pharmacological interventions.

- **Develop and validate sensitive and reliable translational tools to detect and measure mechanistically relevant signatures of biological effect and to measure efficacy and other outcomes.**
- **Conduct preliminary/early phase studies of safety, toxicity, dosing, adherence, control validation, effect/sample sizes, ADME (Absorption, Distribution, Metabolism, and Excretion), and pharmacokinetics.**
- **Build upon established and proven product integrity policies and processes.**

Clinical intervention studies must be grounded on a solid foundation of information derived from basic and clinical translational research. This work requires multidisciplinary research collaborations between basic and clinical scientists.

Maximally informative studies require careful characterization of the intervention, determination of suitable outcome measures, validation of laboratory measures of biological effect, an understanding of pharmacokinetics and pharmacodynamics, rigorous attention to product integrity, and other steps necessary to ensure that later research is as informative as it can be.

Specific efforts are needed to explore the safety profile of specific CAM pharmacological interventions. Given the widespread use of NPs by the public for self care and promotion of wellness—often independent of professional advice—investigation of the short- and long-term safety of these products, including their possible interactions with pharmaceuticals and with other NPs, remains a compelling public health need.

Strategy 1.3: Support targeted large-scale clinical evaluation and intervention studies of carefully selected CAM pharmacological interventions.

A successful clinical trial is one that yields as much information as possible, whether or not the hypothesized clinical benefit is observed. This measure of success is especially important for large clinical trials, given their inherent complexity, expense, and risks. In general, large clinical trials should be based on a strong mechanistic hypothesis supported by basic/exploratory research; a sound body of pharmacokinetic/ADME information; and the translational tools (e.g., laboratory measures of biological effect) needed to maximize knowledge gained. Clinical and laboratory measures of effect must be sensitive enough to detect reasonable and realistic clinical effects or to determine with a high degree of certainty that a negative result is truly negative.

NCCAM investment in large clinical trials of CAM NPs should be highly selective and only made when there is ample scientific and/or public health justification (see Framework for Identifying High Priorities and Areas of Focus). This work requires a well-defined and transparent process for priority setting and a milestone-driven and transparent approach to oversight of progress in the various steps of clinical evaluation.

Studying the Effects of Probiotics on the Human Microbiome

Probiotics are nonpathogenic live microorganisms available in foods and dietary supplements. Examples of foods containing probiotics are yogurt, fermented and unfermented milk, miso, tempeh, and some juices and soy beverages. In probiotic foods and supplements, the bacteria may have been present originally or added during preparation. Some probiotic foods date back to ancient times, such as fermented foods and cultured milk products. Probiotics can introduce deficient or absent microbial components with known benefits to the human host.

Insights gained from the Human Microbiome Project are stimulating research, specifically the role of microbiota in the development of many diseases. New tools, such as high-throughput parallel sequencing and comparative genomics, metabolic profiling and functional genomics, fluorescence in situ hybridization, and phylogenetic microarrays have the potential to elucidate the functional significance of the multiple microbial species that reside in the gut. Importantly, this understanding could explain differences among the microbiomes of individuals that could be explored to tailor personalized treatment strategies for acute and chronic conditions, such as acute gastroenteritis, diarrhea, colitis, inflammatory bowel disease, irritable bowel syndrome, and other disorders.

However, more research is needed in order to draw conclusions. Future studies are needed to determine whether combinations of probiotic strains are more or less effective in childhood versus adulthood, whether oral administration is the best route, whether certain microbes antagonize others, and how environmental and genetic factors interplay with microbiota.

Probiotic research has significant potential applications in the developing world as well. Probiotics could offer relatively low-cost treatments in impoverished and medically underserved regions of the world that suffer from disproportionately high rates of gastroenterological disorders linked to malnutrition, infectious diseases, and dehydration.

Identifying Molecular Targets of Dietary Small Molecules

Traditional medicine approaches, such as Ayurveda and Chinese Medicine, have used medicinal extracts to treat disorders ranging from inflammation to depression. Developing countries continue to rely heavily on ethnobotanical medicines because of their pharmacologically active compounds and apparent benefits. Thus, these extracts have been “clinically tested” in a variety of milieus for centuries and provide a rich source of compounds from which modern medicine might benefit. Recent advances in metabolomics, genomics, biochemical genomics, chemical separation, molecular characterization, and pharmaceutical screening provide an exciting opportunity to better understand the mechanisms of these therapeutics.

The challenge to modern medicine lies in isolating and/or synthesizing the active component of these compounds, elucidating molecular mechanisms, and developing a “modern” pharmaceutical that can meet the requirements of favorable absorption, distribution, metabolism, excretion, and toxicity. In addition, it is difficult to reproduce plant extracts and the biochemical properties of plants harvested at different times and locations. Because of these factors, among others, plant extracts have not been attractive novel pharmaceutical leads in recent years. However, because it is estimated that approximately 250,000 living plant species contain an enormous untapped reserve of bioactive compounds, it could be fruitful to search for yet undiscovered compounds, as well as pursue the mechanisms of compounds currently in use.

For example, the polyphenol curcumin, a component of the curry spice turmeric, is used in Chinese Medicine and Ayurveda to treat rheumatism, fever, intestinal disorders, trauma, and amenorrhea, among other disorders. Although synthesis of curcumin is straightforward, it has low bioavailability, requiring large doses for effectiveness. Research has uncovered the effects of curcumin on numerous cell signaling pathways, for example, its ability to inhibit NF- κ activity, COX-2 and 5-LOX expression, and cytokine release. It also has been shown to bind to thioredoxin reductase and several kinases and receptors. The scientific challenge ahead is to determine which target is mechanistically valid for each biological activity. Thus, the versatility of curcumin is both intriguing and challenging in the context of clinical trials.

STRATEGIC OBJECTIVE 2: ADVANCE RESEARCH ON MIND/BODY AND MANIPULATIVE/MANUAL CAM INTERVENTIONS AND PRACTICES

CAM includes a diverse array of nonpharmacological interventions such as meditation, yoga, acupuncture, chiropractic manipulation, and other mind/body or manipulative/manual techniques or practices. These interventions are grouped together in this plan because from a research perspective they share many common features and present many common challenges. These include, for example: (1) they all involve interventions that directly affect or engage neurobiological, neuromuscular, or neuromechanical processes through nonpharmacological approaches; (2) in general, it is difficult or impossible to mask both the practitioners and the participants involved in clinical research; and (3) some interventions such as acupuncture include components of both mind/body effect and manipulation of soft tissue and muscle fascia.

Mind/body interventions—such as biofeedback, progressive muscle relaxation, meditation, guided imagery, hypnosis, tai chi, qi gong, and yoga—are widely used by individuals seeking to improve health and wellness and sometimes by practitioners in the treatment of difficult symptoms. Compared to results from the 2002 NHIS to the 2007 NHIS, there has been a significant increase in the use of controlled breathing practices, meditation, massage therapy, and yoga.

There is great interest across many health care disciplines regarding the application of meditation to health conditions and problems. This interest is based on emerging evidence from many studies that suggests that meditation and yoga can enhance quality of life, reduce psychological stress, and improve some mental health outcomes. For example, patients faced with chronic and even terminal illnesses—particularly conditions like heart disease and cancer—can learn and employ a variety of mind/body practices to achieve a level of symptom relief, a better quality of life, and, in some cases, improvements in health outcomes. Furthermore, there is a growing body of evidence that mindfulness and other meditation practices engage neurobiological mechanisms involved in cognition, emotion regulation, and behavior. [See box on page 21.]

According to 2007 NHIS data, the most common use of manipulative and body-based CAM interventions by adults is to treat back and/or neck pain, joint pain or stiffness, arthritis pain, and other chronic, painful musculoskeletal conditions. The most common CAM approaches used to treat pain—and the most studied to date—include acupuncture (for many types of pain), spinal manipulation (for low back and neck pain), and massage.

There is much controversy about many manipulative and body-based CAM interventions. The case of acupuncture is illustrative. Explanations of mechanisms of acupuncture effect derived from Traditional Chinese Medicine theory about meridians and the flow of “qi” are inconsistent with contemporary scientific understanding of anatomy and neurophysiology. There also is considerable controversy surrounding many issues regarding clinical trial design

(e.g., choice of control group) and interpretation of existing data from clinical trials. On the other hand, there is a growing body of evidence indicating that the clinical experience of receiving acupuncture (1) is often accompanied by relief of pain; and (2) engages neurobiological mechanisms relevant to regulation of pain perception and control. Unknown at this time are the relative contributions of the specific effects of acupuncture per se and the nonspecific effects of expectancy, placebo, and other factors of context that are also part of the clinical experience. Given limitations and side effects of currently available treatments for chronic pain, it is important to better understand the potential role and contributions of nonpharmacological CAM approaches.

Challenges in Studying These CAM Modalities

Investigators studying CAM mind/body and manual/manipulative interventions face a number of scientifically interesting and important challenges. These include carefully defining the most compelling research question to be addressed, designing a study and choosing appropriate controls to address this question, and responding thoughtfully and appropriately to criticism of study design, which is sometimes legitimate and other times incorporates biases from reviewers' beliefs.

For example, a classical efficacy design incorporating a "sham" intervention may be most appropriate if the research question centers on refining technique or determining a mechanism of action. In other cases, however, if the most compelling and clinically relevant question centers on whether or how the intervention adds value to existing approaches (e.g., to managing a chronic symptom), an effectiveness design that entails comparison to a different treatment (rather than to a "sham" /placebo intervention) may be most appropriate.

Another challenge in designing and executing studies of these CAM practices relates to the fact that many of them are physical procedures, or they are administered or practiced over extended periods of time. This can make it very difficult to standardize practitioner approaches, monitor treatment fidelity or participant compliance, or capture the full range of treatment approaches being pursued by individuals. It is also often the case that true masking of study participants involved in a procedure (e.g., in a study of massage or meditation) is a practical impossibility.

Finally, recent research has found that duration of the patient-practitioner interaction and communication of warmth, empathy, and the possibility of a positive outcome on the part of the practitioner can affect clinical outcomes. A number of nonpharmacologic CAM interventions involve encounters between a health care provider and a patient in which these and other "nonspecific" contextual factors, expectancy, or the placebo response may contribute to outcomes—including patient-centered benefits. Better understanding of the relative roles of specific and nonspecific factors in the patient-practitioner interaction, and the potential for insight into exploitation of both to improve symptom management or general health and well-being, will be valuable and is needed.

Strategies for Addressing Scientific Challenges

Clinical reports of promising effects of mind/body and manual/manipulative practices point toward opportunities to advance the science and practice of symptom management and health promotion. These reports are supported by an equally intriguing and growing body of basic and clinical research in the fields of neuroscience, psychoneuroimmunology, and behavioral medicine. Addressing the scientific and operational challenges confronting study of promising nonpharmacological CAM interventions requires continued efforts to foster multidisciplinary collaboration that aims to engage the expertise and experience of CAM practitioners and the expertise, tools, and technologies of a variety of scientific disciplines, including the neurosciences, behavioral medicine, biomechanics, and physical medicine.

Strategy 2.1: Harness state-of-the art technologies and approaches of the neurobiological, biomechanical, and behavioral sciences to:

- **Elucidate biological effects and mechanisms of action of mind/body and manual/manipulative interventions, practices, and approaches.**
- **Study the interactions between these interventions and the effects of expectancy, the placebo response, and the provider-client/patient relationship.**

As in the case of pharmacological interventions, understanding of biological effects and mechanisms of action is crucial in developing translational tools and in designing and executing maximally informative clinical research. It also is a crucial component of the scientific evidence base. Finally, it will contribute to advancing the overarching goals of better treatment and promotion of health and well-being.

Strategy 2.2: Support translational research to build a solid biological foundation for studies of efficacy or effectiveness of mind/body and manual/manipulative interventions.

Rigorous study of all clinical interventions requires well-established methodology that has undergone careful preliminary assessment and feasibility testing. Large clinical studies are an essential component of the evidence base regarding clinical efficacy or effectiveness, but in order to implement such studies, treatment algorithms need to be developed that can be subjected to multi-site clinical testing and, if shown useful, translated into practice. Methods need to be in place to ensure consistent protocol implementation and to minimize or control for practitioner variability. In addition, well-characterized and meaningful clinical and laboratory outcome measures are needed to accurately assess the scope and magnitude of effects or to definitively discern a lack thereof.

Improvement in translational tools will increase the quality and consistency of clinical trials in CAM and ultimately elucidate new understanding of the clinical utility and applicability of mind/body and manual/manipulative interventions. Many types of studies may be appropriate for developing and validating translational tools, including ancillary collections of new data in ongoing clinical studies, psychometric investigations, and primary validation studies. The clinical research effort will benefit from the following:

- Feasibility assessment of treatment algorithms that will permit rigorous testing of clinical effectiveness and facilitate comparability of research results across studies.
- Methods to assess consistency of practitioner approaches and other aspects of protocol implementation.
- Validated tools for assessment of important contextual factors for CAM mind/body medicine and/or manual therapy interventions (e.g., practitioner skill, patient-practitioner interactions, and/or patient experiences).
- Validated, standardized measures to assess dose effects.
- Intervention-relevant clinical outcome measures and assessment tools.
- Better measures of subjective outcomes.
- Intervention-relevant signatures of biological effect.
- New technology, research tools, instrumentations, or devices to facilitate quantitative measurements of the effects of mind/body or manual/manipulative practices.

Strategy 2.3: Support clinical evaluation and intervention studies of mind/body and manual/manipulative interventions.

In studying this set of CAM interventions, it is particularly important that the research questions most relevant to advancing health and well-being are carefully defined and clearly articulated. Major decisions regarding clinical research design—for example, whether to use a “sham” or “other treatment” control—should follow from this question.

It is also critical to understand a number of considerations related to the specific population under study. Is there a “standard of care” or an accepted treatment for the disease/condition? What would study participants be willing to accept (e.g., treatment burden, random allocation) and how does that affect the likelihood of completing the study? How might factors such as expectancy influence responsiveness or outcomes to the intervention? Is the CAM use intended to treat conditions (e.g., pain, infection, sleeplessness), change behavior (e.g., yoga, meditation), promote overall health (e.g., healthy behavior/lifestyles), or a combination of these goals?

All of these challenges call for creative clinical research designs and approaches that draw on the experience of other fields of biomedical research studying procedural interventions (e.g., surgery), behavior change (e.g., cognitive-behavioral therapy), or outcomes of health interventions in populations.

Understanding the Engagement of Major Pathways of Emotion Regulation by Meditative Practices

Mindfulness research is providing a rapidly growing body of evidence that meditation can train the mind to change the brain and that this ability increases with experience. Recent research has found that systematic mindfulness training and meditation practices influence areas of the brain involved in regulating awareness, attention, and emotion. Brain imaging has shown that more mindful people are able to control emotional reactions and improve self awareness. These practices also have been found to positively affect the immune system. NIH-supported research is investigating the use of mindfulness training in treating specific pain conditions, hypertension, myocardial ischemia, weight control, irritable bowel syndrome, insomnia, HIV/AIDS, and substance abuse. The beneficial physical effects of mindfulness training could be attributable to learning how to cope with stress. Mindfulness meditation is being explored as a means of changing behavior, as, for example, smoking when anxious or eating when depressed.

In summary, studies of mindfulness are uncovering beneficial effects on the mind, the brain, the body, and behavior. Clinical and laboratory studies are documenting alterations in cognition, emotion, biology, and behavior that combine to improve health.

Better Strategies for Managing Back Pain

By any measure, low back pain is a huge public health problem. It affects 1 in 4 adults, and 10 to 15 percent of patients transition from acute to chronic pain. Chronic back pain is, by far, the most frequent health problem for which Americans turn to CAM. Data continue to emerge on a number of fronts suggesting that various conventional and/or CAM interventions may have roles to play in management of chronic back pain.

However, there is little agreement and often controversy among providers on optimal approaches to clinical or laboratory diagnostic evaluation of chronic back pain. Furthermore, many treatment options are offered to patients seeking care or are pursued by individuals searching for self-help approaches—including opioids, injections, surgery, physical therapy, spinal manipulation, yoga, exercise therapy, acupuncture, massage, and cognitive-behavioral therapy. Often patients try different approaches, sometimes in consultation with a provider and sometimes on their own, searching for a strategy or combination of strategies that work, even if temporarily.

Numerous clinical trials have focused on specific conventional and CAM interventions, including behavioral approaches, devices, drugs, surgery, physical or manual therapies, and acupuncture. These studies have found varying degrees of effectiveness and wide disparities in treatment costs. Thus, although there are several options for treatment of low back pain, it is difficult to differentiate which treatment is best for a given individual and under what conditions.

Better understanding of the pathophysiology of back pain will require state-of-the-art research technology applied to elucidating genetics, emotional and cognitive influences, central nervous system responses, behavior, and spinal muscle function and movement. With a better understanding of the natural history and pathophysiology of chronic low back pain, it should be possible to develop more informative interventional studies that also better account for non-specific effects (e.g., expectations, placebo, provider, and setting) and improved population stratifications.

STRATEGIC OBJECTIVE 3: INCREASE UNDERSTANDING OF “REAL-WORLD” PATTERNS AND OUTCOMES OF CAM USE AND ITS INTEGRATION INTO HEALTH CARE AND HEALTH PROMOTION

One of the defining features of CAM is its widespread use by the public. Indeed, NCCAM was established in 1998 because Congress felt that the public health and policy implications of this prevalent use, often in the absence of scientific evidence regarding efficacy or safety, warranted a more focused research effort at NIH. These circumstances lead directly to unique opportunities in the field of CAM research for population-based research addressing three major needs:

- Descriptive information examining the frequency of and reasons for CAM use in disease and symptom treatment and in promoting improved health and well-being, by the general public and in specific subpopulations, using the tools of survey and epidemiology research.
- “Real-world” outcomes information, obtained through use of effectiveness research, cost-effectiveness research, health services research, and related methodological approaches in order to gain insight into the potential or perceived benefits, risks, and comparative effectiveness of CAM use.
- Information on how and why individuals and health care providers decide to use CAM or to adopt behavioral changes often associated with use of CAM practices.

Such research will inform (1) ongoing and future research aimed at assessing the efficacy, safety, and comparative effectiveness of CAM practices; (2) national CAM research priorities and research policy; and (3) national and international activities in the arenas of health and health care policy and health care financing.

Frequency of and Reasons for CAM Use

Strategy 3.1: Use survey and epidemiological methods to do the following:

- **Study patterns of CAM use by individuals and practitioners.**
- **Better understand reasons for CAM use.**
- **Identify safety concerns (e.g., side effects, adverse events) among populations of CAM users.**
- **Develop data that informs assessment of outcomes and clinical effect.**
- **Study patterns of CAM use in specific demographic subpopulations.**

NCCAM has twice supported national population-based surveys of CAM use—in 2002 and 2007. These studies have been carried out in collaboration with the National Center for Health Statistics at the Centers for Disease Control and Prevention as part of the National Health Interview Survey. This body of work has yielded the most comprehensive and

complete picture of Americans' use of CAM and has been instrumental in shaping national and international understanding regarding CAM use, specific CAM research studies, consumer health information initiatives, and public policy related to CAM. The studies also have been instrumental in shaping NCCAM's current strategic thinking and research priorities. For example, this information, together with clinical trial and evidence-based recommendations suggesting the potential usefulness of several specific CAM practices such as chiropractic manipulation, acupuncture, and massage in the management of chronic back pain, has led NCCAM to target chronic back pain as a high priority for future investment.

The NHIS data are also pivotal in shaping NCCAM's approach to its congressional mandate regarding the need to provide evidence-based information to the public and to health care providers. This need is particularly compelling given the enormous quantity of information about CAM now available on the Internet and the highly variable objectivity, scientific validity, and timeliness of that information. Understanding the scope and nature of public use is instrumental in defining priorities for NCCAM and other organizations in developing and disseminating evidence-based information.

Assessing “Real-World” Outcomes of CAM Use

Strategy 3.2: Use a range of research methods—for example, epidemiology, surveys, health services research, effectiveness/cost-effectiveness—to study effectiveness (outcomes) and cost-effectiveness of CAM practices in “real-world” settings.

As noted previously, many CAM interventions are already in widespread use in the general population. For this reason alone, it is important that the methods and approaches of effectiveness research be explored for their application to the clinical study of the role of CAM interventions in treatment and health promotion. This is true, in particular, for approaches that leverage the experience and resources of practice-based or population-based networks in developing a better understanding of the role and relative contributions of CAM practices to integrative medicine. Population-based and practice-based strategies also offer great potential for studying the effectiveness of CAM-related interventions in engaging the patient/client in health-promoting behaviors and practices. In this context, it is noteworthy that 5 of the top 100 topics identified by the Institute of Medicine as priorities for comparative effectiveness research involve CAM approaches. Finally, the methods and approaches of effectiveness research also offer potential to address, at least in part, a frequently voiced concern that CAM research often fails to reflect the actual practice or use of CAM in real-world settings.

In addition, there is a need for innovation, creativity, and the development of better tools for research on the value of integrating CAM and conventional medical approaches, which can best be approached by leveraging the experience of existing practice-based or population-based networks or initiatives. The types of outcomes of particular interest

include well-being, functional status, quality of life, patient satisfaction, and costs, in addition to measures of morbidity and changes in disease status. It is important to understand how CAM use (either a simple intervention or a group of interventions) affects patient outcomes and whether there are differences among populations, among modalities, or among conditions or goals. Does the use of CAM affect patient satisfaction or wellness or make a difference in the functional result of care? Are CAM users more amenable to behavior change to improve health, and what roles do CAM providers play in motivating change?

Of considerable importance is studying the effectiveness of CAM when combined with conventional care in a multidisciplinary, integrated health care environment. Does the environment in which some CAM modalities are offered affect patient outcomes (e.g., one-on-one “healing” environments versus large health care institutions)? Are individuals more or less receptive to CAM when it is self-prescribed versus recommended by a conventional health care provider? Sorting out the relative influences of the health care environment on outcomes is essential to understanding the effects and effectiveness of CAM.

Studying CAM’s Role in Promoting Health Behaviors

Strategy 3.3: Conduct research on CAM decisionmaking and the role of CAM in behavior change. Such studies will illuminate the following:

- **Value of CAM modalities in a variety of person-centered outcomes and in motivating behavioral change.**
- **Acceptance and adoption of CAM modalities by individuals.**
- **Potential contributions to and acceptance or adoption of CAM practices by health care systems.**

Several studies suggest associations between CAM use and positive health behaviors and use of other preventive medicine strategies. For example, data suggest that some CAM users are more likely to exercise regularly than non-CAM users. Other data suggest that individuals who see both CAM and conventional medical providers are more health conscious and proactive about their health than are those who see only CAM or only conventional medicine providers. Finally, a noteworthy degree of success in motivating and sustaining healthy behavior change is often claimed by CAM and integrative medicine practitioners. It is premature to attribute cause and effect to these associations or to accept the claims at face value. Nonetheless, they are intriguing and deserve further exploration. Given widely recognized limitations of current strategies for health behavior change, better understanding of the role of CAM practices and interventions in promoting health and health-seeking behavior should be explored.

Importance of the Practitioner-Patient Interaction, Context Effects, and the Placebo Response

One theory about the placebo effect focuses on the benefits of receiving “care” from a supportive or caring practitioner. Encounters between a health care provider and a patient provide a context against which the relative effect of the administered intervention has to be measured. That is, how much does the caring interaction influence response to the intervention alone?

In a randomized controlled trial of patients with irritable bowel syndrome, researchers attempted to tease out the components of treatment effects using three arms: observation, placebo acupuncture alone, and placebo acupuncture with an augmented patient-provider relationship. It was hypothesized that the distinct contributions of observation and assessment, response to the administration of an intervention, and response to the patient-practitioner interaction all play a role in treatment effects. Irritable bowel syndrome was selected as a suitable disease for study because previous studies have shown a large positive response (40 percent) to placebo. The investigators were able to disentangle the relative effects of each aspect of the intervention, with the arm receiving placebo acupuncture with augmented care showing the most potent effect. Patients in this arm showed a decrease in symptom severity, with improvement lasting as long as 6 weeks or more. The authors of the study concluded that warmth, empathy, duration of the interaction, and the communication of a positive outcome effected clinical outcomes. Future studies are needed to better understand the mechanisms of such nonspecific effects.

STRATEGIC OBJECTIVE 4: IMPROVE THE CAPACITY OF THE FIELD TO CARRY OUT RIGOROUS RESEARCH

When Congress established NCCAM, it recognized the need to build research capacity in the field, and it authorized NCCAM to use a variety of research training and career development award mechanisms to ensure that there would be a cadre of highly qualified CAM and conventional investigators to carry out NCCAM's research mission. These efforts have been successful in attracting many conventional and CAM-trained scientists into the field of CAM research. A robust and highly collaborative community of investigators now employs and develops state-of-the-art research methods and tools in studying the safety and usefulness of CAM interventions.

Significant growth in the quality and quantity of the evidence base regarding CAM reflects this growth in CAM research capacity. In the past 10 years, NCCAM has funded more than 2,500 research projects resulting in more than 3,300 scientific articles in peer-reviewed journals. Nonetheless, as described in the first three Strategic Objectives, there remain numerous challenges that must be addressed to support rigorous research on the role of CAM interventions in improving health and well-being.

To pursue these questions successfully, NCCAM must continue to ensure that the human talent, resources, and infrastructure needed to design and carry out the highest quality research are in place, that they involve collaborative multidisciplinary research partnerships across a broad spectrum of disciplines and experiences, and that maximum advantage is taken of opportunities to leverage scientific resources and experience.

Strategy 4.1: Continue to develop and support high-quality research training and career development opportunities to increase the number, quality, and diversity of CAM researchers.

A successful and robust CAM research enterprise must draw from two sources of well-trained, skilled, and experienced talent: CAM practitioners and conventional biomedical/behavioral scientists. CAM practitioners are key holders of knowledge related to CAM therapies. NCCAM has always recognized the need for research training and career development efforts targeted specifically toward this diverse community. Over the years the Center has developed a number of programs aimed at enhancing CAM practitioners' abilities to critically evaluate biomedical literature, develop greater knowledge of the therapies prescribed to their patients by allopathic physicians in integrative medicine settings, become better able to participate in clinical research, and, in some cases, be inspired to seek advanced training and career development opportunities in biomedical research.

Researchers from many different biomedical and behavioral disciplines are key holders of the scientific knowledge required for indepth investigation of the basic biological, physiological, and clinical effects of CAM interventions. Over the years NCCAM has also

targeted resources aimed at attracting well-trained and experienced scientists into CAM research and in supporting their interests and involvement in the field.

To maintain a vibrant, productive, multidisciplinary, and diverse research enterprise, NCCAM will continue to provide support for a variety of specialized high-quality research training and career development opportunities. In particular, the Center will focus on:

- Postdoctoral students who are interested in pursuing a career in CAM research.
- CAM practitioners who wish to gain the knowledge and experience needed to engage in rigorous collaborative research in their field.
- Conventional medical researchers and practitioners who need to increase their base of knowledge and experience regarding specific CAM interventions and practices.
- Members of populations who are underrepresented in scientific research and are interested in careers in CAM research.

Strategy 4.2: Continue to build and foster cross-disciplinary and multidisciplinary collaboration and partnerships to conduct CAM research.

It is widely recognized across the field of biomedical and behavioral research that clinical investigation to provide evidence useful to the public, health care providers and health policymakers is an inherently multidisciplinary enterprise. This is no less true of the field of CAM research. Rigorous investigation in this field clearly requires cross-disciplinary and multidisciplinary teams working within and across institutions and settings.

For example, the development of effective translational research tools for CAM research requires indepth understanding of the interventions, the health conditions under study, and the tools and technologies of other basic and clinical scientific disciplines. This can only be achieved through partnerships between institutions and practitioners with particular expertise in CAM and institutions and individuals with relevant research expertise. NCCAM will continue to promote and make the most of collaborative and strategic partnerships to enrich the field of CAM research with the experience of other fields and to adopt or adapt research tools and techniques.

Strategy 4.3: Continue to leverage scientific and information resources of other fields and organizations.

There are relatively few incentives for private-sector investment in CAM research. As a consequence, NCCAM's investments in building evidence regarding safety and usefulness and in increasing the capacity for CAM research are particularly important. Although the Center continues to take the lead among Federal agencies in CAM research, it cannot pursue its mission in isolation.

For example, given the breadth of NCCAM's mission, it must often turn to the expertise, experience, and resources of its sister NIH institutes and centers. Collaborations with other NIH institutes and centers in the past have yielded significant payoffs in advancing knowledge of CAM and disseminating the research results. NCCAM will continue to

leverage its privileged position as a component of NIH and actively seek opportunities and partners in areas of shared interest.

In addition, CAM, integrative medicine, and traditional medicine are now a specific focus of interest of many national and international scientific and professional organizations, national governments, and the World Health Organization. NCCAM will continue to identify opportunities in which collaborative research and training efforts promise to yield mutual benefits.

STRATEGIC OBJECTIVE 5: DEVELOP AND DISSEMINATE OBJECTIVE, EVIDENCE-BASED INFORMATION ON CAM INTERVENTIONS

Public interest in CAM remains strong. People are often using CAM without the advice or guidance of a health care provider—whether conventional or CAM. Educating the public to be informed consumers of CAM is one of NCCAM’s primary communications goals.

The translation and dissemination of evidence-based health information to the public and health care providers is a key component of NIH’s mission. Because NIH plays a significant role in the health of the Nation and is supported by taxpayer dollars, it is essential that the public have ready access to the unbiased, authoritative health and medical information that NIH produces every day.

As a component of NIH, NCCAM shares in the mandate to communicate regularly about research advances and the latest health and science information on CAM. The fact that NCCAM’s communication efforts usually concern the state of evidence regarding products or practices that are readily available to consumers, and are widely used as “self-care” interventions, underscores the central importance of NCCAM’s information activities.

Challenges

NCCAM shares with its sister NIH institutes and centers many of the challenges of translating and delivering complex scientific information to an interested public. In this regard, two features of the landscape of complementary and alternative medicine in the United States are noteworthy. First, the public domain is deluged with information about CAM, some of it overtly promotional, and much of it either not evidence-based or of questionable quality and reliability. NCCAM must strike a careful balance in its presentation of the state of evidence—which is rarely definitive—so that the information is scientifically objective and appropriately balanced regarding usefulness and safety.

Second, NCCAM’s constituencies include consumers who are curious about what the science says, as well as individuals with strong, often polar-opposite beliefs or biases regarding the state of evidence regarding particular CAM interventions or even the need for CAM research. In this context, the same evidence-based information can appear to some as promoting unproven or dangerous practices and to others as discrediting practices with proven safety and value.

Strategy 5.1: Provide reliable, objective, and evidence-based information to help the public make informed decisions about CAM.

NCCAM uses a variety of communication mechanisms to explain to the public what is known about the science of CAM without bias or preconceived ideas and to provide a

balanced perspective on the promise as well as the concerns of using CAM. Given the array of public information surrounding CAM, the Center seeks to provide an objective voice to help the public and providers make informed health care decisions.

NCCAM will continue to provide information in a variety of formats to its audiences through multiple channels including the Web, broadcast and print media, its Clearinghouse, the exhibit program, and social media. Importantly, as the evidence base continues to evolve, NCCAM will be able to draw more and more on the evidence-based interpretations or conclusions of independent organizations and professional societies. NCCAM will collaborate with these and other third-party organizations and other Government agencies to ensure that information reaches its many stakeholder audiences and that opportunities to leverage communication resources are maximized.

The field of communications evolves rapidly. The Internet is a key source of information, with 8 in 10 Internet users (or two-thirds of U.S. adults) looking online for health information. Online communities are continuously springing up, bringing together groups of people who share information and resources with each other. Social media sites are replacing the standard search engines as the most frequent destinations for online users. Mobile phones and other devices are fast replacing personal computers. In order to ensure that those interested in CAM research find NCCAM's information, it is incumbent on the Center to use these emerging technologies.

Finally, NCCAM strives to address its information and resources to the large majority of consumers and health care providers who are curious about what the science says, even when the evidence is inconclusive or does not lead to clear guidance. To accomplish this, NCCAM will continue to work actively with its diverse community of stakeholders to identify, understand, and address the CAM information needs of consumers and health care providers and their concerns about accuracy or interpretation of research results or health messages.

Strategy 5.2: Provide reliable, objective, and evidence-based information about CAM to help health care providers manage patient care and support healthier lifestyles.

Health care professionals—both conventional and CAM—also confront many challenges in accessing current scientific information about CAM. Recognizing these challenges, NCCAM has initiated efforts to develop information resources targeted toward the needs of this important audience. These resources include specialized communications, an exhibit program, outreach to professional societies, and online tools, including a dedicated Web portal that includes research findings as well as links to clinical practice guidelines. These communication efforts help ensure that health care providers have reliable information and authoritative resources on CAM and facilitate evidence-based integration of safe and effective CAM practices into comprehensive programs of health care and health promotion.

Strategy 5.3: Enable an integrative dialogue with consumers and health care providers about CAM use and its role in treatment and health promotion.

A 2006 NCCAM/AARP survey of individuals age 50 or older revealed that while more than two-thirds of respondents used some form of CAM, less than one-third of CAM users had talked to their physicians about it. The main reasons given for not talking about CAM use were that respondents did not know they should discuss CAM and that their physicians never asked.

Ensuring safe and integrated health care requires a partnership between the health care provider—whether conventional or CAM—and the patient. In an effective partnership, there is communication about the full range of health care interventions and the health practices patients are using.

NCCAM's "Time To Talk" campaign provides tools to facilitate conversation about CAM use between health care providers and patients. NCCAM will explore expansion of this program to additional audiences—including CAM providers and a more diverse community of consumers—as well as harnessing new communication channels and technologies to enhance this important dialogue.